

### **REMARKS**

Claims 1-33 and 37 have been cancelled without prejudice or disclaimer. Claims 34-36 and 38-56 are pending in this application. Claim 34 is amended for additional clarity by incorporating the subject matter of the canceled claim 37. Claims 38-39 are amended to correct their dependencies. Therefore, no new matter is introduced. The Office Action is discussed below:

#### ***Anticipation Rejections:***

On pages 2-5 of the Office Action, the Examiner has rejected claims 34-44, 46, 48, 49, 51-53, 55, and 56 under 35 U.S.C. 102(b) allegedly as being anticipated by Kavanagh *et al.* (WO 86/103394). Applicants respectfully disagree and submit that the Examiner has misinterpreted the disclosure of Kavanagh *et al.*

In alleging that claim 34 lacks novelty over Kavanagh, the Examiner identifies in Kavanagh an upper portion (denoted by A on the Examiner's annotated figure), a valve portion 15, a sample chamber 10, a valve inlet (C), and a valve outlet (D). Clearly, the valve outlet is positioned substantially below the valve inlet. The Examiner determines that Kavanagh comprises a shut-off chamber separating the valve inlet from the valve outlet, and this shut-off chamber is defined by the dimensions of the working parts of valve elements B on his annotated drawing. The Examiner then identifies capillary tube 16 as a shut-off valve, and the internal space of capillary tube 16 as a shut-off chamber overflow.

The structure and working of the sampler of Kavanagh is described in the abstract. Liquid enters the funnel and passes through a length of flexible tubing 14, and from there into a container. Once the level of liquid reaches the bottom of the capillary tube 16 substantially no further liquid can enter the container. At this point the shut-off valve 15 is closed to prevent any further liquid from passing down the inlet tube. This shut-off valve closes the flexible tubing by means of pinching the flexible tubing so that no fluid path exists within it. Thus, the shut-off valve of Kavanagh is a mechanical element that pinches a length of flexible tubing.

The Examiner equates the shut-off valve 15 of Kavanagh with the valve portion defined in present claim 34.

The valve portion of claim 34 comprises “a valve inlet coupled to the sampler inlet; a valve outlet opening into the sample chamber, wherein the valve outlet is positioned substantially below the valve inlet;

a vent tube extending between the vent inlet and the vent outlet, wherein the vent inlet is positioned within the sample chamber and the vent outlet is positioned at a level above the valve outlet;

*a shut-off chamber separating the valve inlet from the valve outlet; and*

*a shut-off chamber overflow -comprising a valve overflow leading out of the shut-off chamber,....”*

The shut-off valve of Kavanagh is merely a length of flexible tubing that can act as a valve because it can be pinched to close its internal bore. Logically, this tube has an inlet and an outlet, but there is no shut-off chamber separating the valve inlet from the valve outlet as defined in claim 34. When the shut-off valve is open the tube is unaffected. When the shut-off valve is closed the flexible tube is pinched together at a point, thereby preventing further passage of liquid through the tube. No chamber is defined between the inlet and the outlet of the Kavanagh tubing. For this reason alone claim 34 is novel over Kavanagh.

The Examiner states that the capillary tube 16 is a shut-off valve and the internal space of the capillary tube is a shut-off overflow as recited in claim 34. It is first noted that if the capillary tube acted as an overflow for liquid it could not also function to prevent liquid entering the container when the level of liquid reached the bottom of the capillary tube. Furthermore, the shut-off chamber and shut-off chamber overflow as recited in claim 34 are comprised in the valve portion of the sampler. The shut-off chamber as recited in claim 34 separates the valve inlet from the valve outlet. The capillary tube 16 of Kavanagh is clearly not between a valve inlet and a valve outlet, in particular not between the valve inlet and outlet as identified by the Examiner by letters C and D on the annotated diagram on page 3 of the Office Action.

Claim 34 recites a shut-off overflow comprising "a valve overflow leading out of the shut-off chamber." The Examiner has defined the shut-off chamber as being the portion of the flexible tubing between the working parts of the valve elements. There is no overflow leading out of this region of Kavanagh.

In this regard, applicants refer the Examiner to the dictates of the MPEP that:

"A PRIOR ART DEVICE CAN PERFORM ALL THE FUNCTIONS OF THE APPARATUS CLAIM AND STILL NOT ANTICIPATE THE CLAIM

Even if the prior art device performs all the functions recited in the claim, the prior art cannot anticipate the claim if there is any structural difference..... *In re Ruskin*, 347 F.2d 843, 146 USPQ 211 (CCPA 1965) as implicitly modified by *In re Donaldson*, 16 F.3d 1189, 29 USPQ2d 1845 (Fed. Cir. 1994). See also *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1951 (Fed. Cir. 1999)...."

See MPEP §2114 (Rev. 6, September 2007 at 2100-53).

Applicants also refer the examiner that:

Not only must all of the elements recited in the claim be present, the elements must be "arranged or combined in the same way" as recited in the claim in order for anticipation to be found. See *Net MoneyIN Inc. v. VeriSign Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008).

It is clear that the sampler as recited in claim 34 has an arranged structure that is completely different structure than the sampler disclosed by Kavanagh. The design of the sampler of claim 34 allows a sample chamber to be filled and once the flow is shut off by a valve portion, remaining liquid overflows from a shut-off chamber. This is particularly advantageous in the sampling of urine where any unwanted overflow can be controllably directed for subsequent collection or for sanitary disposal. By contrast, in the sampler disclosed by Kavanagh there is no overflow provided for excess liquid such as urine. Once the desired volume of sample has been taken and the valve closed, there is no place for excess urine to go apart from to fill the funnel 12.

For additional clarity, applicants amend claim 34 to recite "a vent tube extending between a vent inlet and a vent outlet, wherein the vent inlet is positioned within the sample chamber and the vent outlet is positioned at a level above the valve outlet...."

The amended claim 34 further defines that the valve portion comprises a vent tube extending between a vent inlet and vent outlet.

The sampler of claim 34 operates in a different way to Kavanagh using a different structure and provides substantial benefits over the device of Kavanagh. Therefore, the claimed invention is both novel and inventive over Kavanagh.

Independent claim 51 defines a method for sampling a first portion of a liquid flow using a sampler as defined in claim 34. In section 13, on page 5, of the Office Action, the Examiner objects that claim 51 is not novel over Kavanagh. The Examiner's misinterpretation of Kavanagh has already been discussed above. In addition, the Examiner has not considered the step defined in claim 51 in which "*further liquid flow into the valve portion of the sampler is diverted through the shut-off chamber and drains through the shut-off chamber overflow*". As Kavanagh neither has a shut-off chamber nor an overflow leading from the shut-off chamber through which further liquid flow into the valve portion could pass. In this context, applicants invite the Examiner to consider the MPEP, which states:

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "When a claim covers several structures or compositions, either generically or as alternatives, the claim is deemed anticipated if any of the structures or compositions within the scope of the claim is known in the prior art." *Brown v. 3M*, 265 F.3d 1349, 1351, 60 USPQ2d 1375, 1376 (Fed. Cir. 2001) ..... "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

See MPEP §2131 (Rev. 6, September 2007 at 2100-67).

The Federal Circuit has ruled that to anticipate, the reference "must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements 'arranged as in the claim'." See *Net MoneyIN Inc. v. VeriSign Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008). Also, see, for example, *In re Arkley*, 455 F.2d 586, 587 (CCPA 1972). A "reference must clearly and unequivocally disclose the claimed [invention]....without any need for picking, choosing, and combining various

disclosures not directly related to each other...." See *Sanofi-Synthelabo v. Apotex, Inc.*, Fed. Cir., No. 2007-1438 (December 12, 2008).

In view of the above, applicants submit that the claimed invention is structurally and functionally different from what is disclosed in Kavanagh. In addition, Kavanagh does not disclose each and every element nor arranged or combined in the same way as set forth in the claimed invention. Therefore, Kavanagh does not anticipate the claimed invention. Accordingly, withdrawal of the anticipation rejection is solicited.

***Obviousness Rejections:***

On pages 5-7 of the Office Action, the Examiner has rejected claim 45 under 35 U.S.C. 103(a) allegedly as being unpatentable over Kavanagh *et al.* (WO 86/103394) in view of Cheng (US 3,010,805). According to the Examiner, Kavanagh discloses the invention as discussed above, as applied to claim 44, but does not expressly disclose the sampler, wherein the funnel of sampler comprises a baffle for reducing turbulence within the device. The Examiner interprets that Cheng discloses a funnel comprising a baffle 105 (refers to Fig. 2) for reducing turbulence within the device (refers to col. 2, lines 65-68). According to the Examiner, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the funnel of Kavanagh with the baffle, as taught by Cheng in order to reduce turbulence within the device (refers to Cheng, col. 1, lines 61-67).

Also, on pages 7-8 of the Office Action, the Examiner has rejected claims 47, 50, and 54 under 35 U.S.C. 103(a) allegedly as being unpatentable over Kavanagh *et al.* (WO 86/103394) in view of McDonald (US 3,982,898).

The Examiner asserts that Kavanagh discloses the claimed invention as discussed above, as applied to claims 34 and 48, but does not expressly disclose the sampler comprising a second collection means for separation different portions liquid flow. Regarding claim 54, the Examiner asserts that Kavanagh discloses the claimed invention as discussed above, as applied to claim 51, but does not expressly disclose the method for collecting a second portion of the liquid flow, wherein the second liquid

flow portion is other than a first portion of the liquid flow. However, the Examiner believes that McDonald discloses the method of urine collection by the device comprising a plurality of chambers for separating different portions of urine samples.

In sum, the Examiner asserts that the combination of Kavanagh and Cheng, and combination of Kavanagh and McDonald, render various claims obvious and unpatentable over the combination of the cited references. Again, applicants disagree with the Examiner and refer to above clarifications that the claimed invention is structurally and functionally different from Kavanagh. Applicants submit that Cheng and McDonald do not rectify the deficiencies of Kavanagh, therefore, a combination of these references does not render the claimed invention obvious.

Applicants also invite the Examiner to consider the MPEP, which states:

“A *prima facie* case of obviousness based on structural similarity is rebuttable by proof that the claimed compounds possess unexpectedly advantageous or superior properties. *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963).”

See MPEP §2144.09 (VII) (Rev. 6, September 2007 at 2100-162).


As discussed above, the sampler of claim 34 operates in a different way to Kavanagh using a different structure and provides substantial benefits over the device of Kavanagh. Therefore, applicants submit that a *prima facie* case of obviousness has not been established by the Examiner, accordingly, withdrawal of the obviousness rejection is solicited.

**REMARKS**

Applicants submit that claims 34-36 and 38-56 are in condition for allowance and request consideration to that effect. The Examiner is invited to contact the undersigned at (202) 416-6800 should there be any questions.

Respectfully submitted,

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Date

  
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